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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/336,091	06/18/99	VAN SNICK, J	L0461/7063-J

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EXAMINER	
SCHWADRON, R	
ART UNIT	**PAPER NUMBER**
1644	11

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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1- File Copy

Office Action Summary

Application No.	Applicant(s)
09/336,091	Van Snick et al.
Examiner	**Art Unit**
Ron Schwadron, Ph.D.	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on 11/2/2000, 11/13/2000 and 2/26/2001

2a) [ ] This action is **FINAL**. 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) 1, 2, 5, 7, 9, 11, 14, 16, 18, 21, 23, 29, 33, 37, 43, 50, 57, 61, 68, 72, 76-83 is/are pending in the application.

4a) Of the above, claim(s) 16, 18, 21, 23, 29, 33, 37, 43, 50, 57, 61, 68, 72 is/are withdrawn from consideration

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) 1, 2, 5, 7, 9, 11, 14, 76-83 is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are objected to by the Examiner.

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____.
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) [X] Notice of References Cited (PTO-892)
16) [X] Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) [X] Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) [ ] Interview Summary (PTO-413) Paper No(s). _____
19) [ ] Notice of Informal Patent Application (PTO-152)
20) [ ] Other:

1. Applicant's election of Group I and the species SEQ. ID. NO. 7 in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 16,18,21,23,29,33,37,43,50,57,61,68,72 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions. Election was made **without** traverse in Paper No. 6.

3. Applicant's election with traverse of the species D-amino acids and endosomal targeting portion of Ii chain in Paper No. 10 is acknowledged. The traversal is on the ground(s) stated in Paper No. 10. This is not found persuasive because it would require a substantial additional burden to search the additional species.

4. Claims 1,2,5,7,9,11,14,76-83 are under consideration.

5. Formal drawings have been submitted which fail to comply with 37 CFR 1.84. Please see the enclosed form PTO-948.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1,2,5,7,9,11,14,76-83 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed peptides/composition containing said peptides.

The instant claims encompass MAGE A1 peptides that bind a HLA class II molecule or a variant of said peptide. The art recognizes that there are at least 150 different allotypes of MHC class II molecules found in humans. The specification discloses three MAGE A1 peptides which bind MHC class II that is derived from only 1 of the at least 150 different allotypes of MHC class II molecules found in humans. In addition, regarding claims that recite "functional variant" said term encompasses a vast number of undescribed peptides which have the functional properties recited in the claim. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. In the instant case, the specification has disclosed three MAGE A1 peptides that bind a single allele of human DR wherein at least 150 different alleles of human DR are known. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if

one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

Claims 76,77,81,82 would not be included in this rejection if rewritten as independent claims.

8. Regarding the term "isolated" as per recited in the claims, said term is interpreted as per the definition of said term in the specification, page 12, lines 12-24.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

10. Claims 1,2,9,11,76,80,81,82 are rejected under 35 U.S.C. 102(b) as being anticipated by Fikes et al. (WO 95/04542).

Fikes et al. teach a peptide comprising SEQ. ID. no. 7 (see page 14, last paragraph to page

16 and claim 8, wherein said vector produces the peptide comprising SEQ. ID. no. 7). Said peptide is derived from MAGE A1 (alias MAGE 1). It is an inherent property of the SEQ. ID. no. 7 portion of said peptide that it binds HLA class II. Said peptide also contains a MAGE 1 HLA class I binding peptide (eg. it is a polytope polypeptide). Regarding claim 82, said claim encompasses a peptide than contains other amino acid sequences (eg. at least an additional class I binding peptide). Therefore, the peptide taught by Fikes et al., page 14 has a peptide that consists of SEQ. ID. No. 7.

11. Claims 1,2,9,11,80 are rejected under 35 U.S.C. 102(b) as being anticipated by Topalian et al. (WO 97/11669).

Topalian et al. teach a peptide derived from MAGE-1 which binds MHC class II (see claims 61, 57-60 and pages 8,28 and 29). Said peptide can also contain a HLA class I binding peptide derived from MAGE 1(eg. it is a polytope polypeptide, see page 27, last paragraph, continued on next page). Topalian et al. teach a peptide that is a functional variant of the peptide recited in claim 2 (see claim 2, wherein said peptide binds MHC class II and stimulates T cells).

12. Claims 1,2 are rejected under 35 U.S.C. 102(a) as being anticipated by Chaux et al.

Chaux et al. teach a peptide derived from MAGE-1 which binds MHC class II (see page 774, column 1, first paragraph). Said peptide is a functional variant of the peptide recited in claim 2 because it binds MHC class II and stimulates T cells.

13. Claims 1,2,5,7,9,11,14,78-80,83 are rejected under 35 U.S.C. 102(a) as being anticipated by Thielemans et al. (WO 99/14326).

Thielemans et al. teach a functional variant of the peptide of claim 2 which binds MHC class II and stimulates T cells (see claim 4). Thielemans et al. teach that said peptide can comprise a Ii chain derived endosomal targeting signal (see claim 7). Thielemans teach that said peptide can comprise a D-amino acid (see claim 9). Thielemans et al. teach that said peptide can be conjugated to a MAGE 1 class I binding peptide (see Table 1 and pages 27-29).

14. Claims 1,2,5,7,78,79 are rejected under 35 U.S.C. 102(e) as being anticipated by Chaux et al. (US Patent 5,965,535).

Chaux et al. teach a functional variant of the peptide of claim 2 which binds MHC class

II and stimulates T cells (see claim 3). Chaux et al. teach that said peptide can comprise a Ii chain derived endosomal targeting signal (see column 14). Thielemans teach that said peptide can comprise a D-amino acid (see claim 9). Thielemans et al. teach that said peptide can be conjugated to a MAGE 1 class I binding peptide (see Table 1 and pages 27-29).

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not he ohtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences hetween the subject matter sought to he patented and the prior art are such that the subject matter as a whole would have beon ohvious at tbe time the invention was made to a person having ordinary skill in the art to which said suhject matter pertains. Patentahility shall not be ncgatived hy the manner in which the invention was made.

16. Claims 1,2,9,11,76,77,80-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fikes et al. (WO 95/04542).

Fikes et al. teach a peptide comprising SEQ. ID. no. 7 (see page 14, last paragraph to page 16 and claim 8, wherein said vector produces the peptide comprising SEQ. ID. no. 7). Said peptide is derived from MAGE A1 (alias MAGE 1). The SEQ. ID. no. 7 portion of said peptide binds HLA class II. Said peptide also contains an HLA class 1 binding peptide (eg. it is a polytope polypeptide). Regarding claim 82, said claim encompasses a peptide than contains other amino acid seqeunces (eg. at least an additional class I binding peptide). Therefore, the peptide taught by Fikes et al., page 14 has a peptide that consists of SEQ. ID. No. 7. Fikes et al. do not teach the peptide of claim 77. Fikes et al. teach a peptide that contains all of the amino acids of SEQ. ID. No. 7 except the first and last two amino acids (see claim 3). Fikes et al. teach that the peptide can include additional amino acids at both ends (see page 5, penultimate paragraph). Fikes et al. teach that the peptide can be less than 15 amino acids. Fikes et al. teach the MAGE I residues that flank both sides of the peptide recited in claims 3 (see page 4, last paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Fikes et al. teach a peptide that contains all of the amino acids of SEQ. ID. No. 7 except the first and last two amino acids and that the peptide can include additional amino acids at both ends and can be less than 15 amino acids. One of ordinary skill in the art would have been motivate to do the aforementioned because Fikes et al. teach that the peptide can include additional amino acids at

both ends and that the peptide can be less than 15 amino acids.

17. Claims 5,14,78,83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fikes et al. (WO 95/04542) as applied to claims 1,2,9,11,76,77,80,81 above, and further in view of Sanderson et al.

The previous rejection teaches the claimed invention except for use of a Ii chain derived endosomal targeting signal. Fikes et al. teach MAGE I peptide conjugates containing a MAGE 1 class binding peptide and a MAGE 1 class II binding peptide (see page 12, last paragraph). Sanderson et al. teach that addition of a Ii chain derived endosomal targeting signal to a peptide can be used to efficiently target a peptide for MHC class II binding/T cell recognition (see abstract). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Fikes et al. teach MAGE 1 peptide conjugates containing a MAGE I class binding peptide and a MAGE I class II binding peptide while Sanderson et al. teach that addition of a Ii chain derived endosomal targeting signal to a peptide can be used to efficiently target a peptide for MHC class II binding/T cell recognition. One of ordinary skill in the art would have been motivate to do the aforementioned because Sanderson et al. teach that addition of a Ii chain derived endosomal targeting signal to a peptide can be used to efficiently target a peptide for MHC class II binding/T cell recognition.

18. Claims 1,2,5,9,11,14,78,80,83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Topalian et al. (WO 97/11669) in view of Sanderson et al.

Topalian et al. teach a peptide derived from MAGE-1 which binds MHC class II (see claims 61, 57-60 and pages 8,28 and 29). Said peptide can also contain a HLA class I binding peptide derived from MAGE 1(eg. it is a polytope polypeptide, see page 27, last paragraph, continued on next page). Topalian et al. teach a peptide that is a functional variant of the peptide recited in claim 2 (see claim 2, wherein said peptide binds MHC class II and stimulates T cells). Topalian et al. do not teach a peptide that has a Ii chain derived endosomal targeting signal. Sanderson et al. teach that addition of a Ii chain derived endosomal targeting signal to a peptide can be used to efficiently target a peptide for MHC class II binding/T cell recognition (see abstract). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Topalian teaches the claimed peptides except for a peptide that has a Ii chain derived endosomal targeting signal, while

Sanderson et al. teach that addition of a Ii chain derived endosomal targeting signal to a peptide can be used to efficiently target a peptide for MHC class II binding/T cell recognition. One of ordinary skill in the art would have been motivate to do the aforementioned because Sanderson et al. teach that addition of a Ii chain derived endosomal targeting signal to a peptide can be used to efficiently target a peptide for MHC class II binding/T cell recognition.

19. Claims 7,79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fikes et al. (WO 95/04542) as applied to claims 1,2,9,11,76,77,80-82 above, and further in view of Gelder et al. (US Patent 6,043,347).

The previous rejection teaches the claimed invention except for a peptide containing D-amino acids. Gelder et al. teach modified peptides containing D-amino acids (see column 20) and that such peptides have increased stability (see column 20). Said peptides would also be non-hydrolyzable because D-amino acid modified peptides have this property (eg. see claim 7 upon which claim 79 depends). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Fikes et al. teach the claimed peptide except for D-amino acid modification, while Gelder et al. teach modified peptides containing D-amino acids (see column 20) and that such peptides exhibit increased stability. One of ordinary skill in the art would have been motivate to do the aforementioned because Gelder et al. that teach modified peptides containing D-amino acids have increased stability.

20. Claims 1,2,5,9,11,14,78,80,83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Topalian et al. (WO 97/11669) in view of Gelder et al. (US Patent 6,043,347).

Topalian et al. teach a peptide derived from MAGE-1 which binds MHC class II (see claims 61, 57-60 and pages 8,28 and 29). Said peptide can also contain an HLA class I binding peptide derived from MAGE 1(eg. it is a polytope polypeptide, see page 27, last paragraph, continued on next page). Topalian et al. teach a peptide that is a functional variant of the peptide recited in claim 2 (see claim 2, wherein said peptide binds MHC class II and stimulates T cells). Topalian et al. do not teach a peptide containing D-amino acids. Gelder et al. teach modified peptides containing D-amino acids (see column 20) and that such peptides increased stability (see column 20). Said peptides would also be non-hydrolyzable because D-amino acid modified peptides have this property (eg. see claim 7 upon which claim 79 depends). It would have been

prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Topalian et al. teach the claimed peptide except for D-amino acid modification, while Gelder et al. teach modified peptides containing D-amino acids (see column 20) and that such peptides increased stability. One of ordinary skill in the art would have been motivate to do the aforementioned because Gelder et al. that teach modified peptides containing D-amino acids have increased stability.

21. No claim is allowed.

22. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

23. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on thc examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-3974. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

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PRIMARY EXAMINER
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